



THE REGULATOR

FOR THE WELL INFORMED LABORATORY



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Hipaa in the news

HIPPA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The Centers for Medicare and Medicaid Services (CMS) have a web site for the parts of HIPAA under CMS jurisdiction. The web site is: www.cms.hhs.gov/hipaa.

This site contains information about Title I and Title II of the Act. Title I concerns health insurance coverage for workers when they change or lose their jobs.

Title II of the Act requires CMS to establish national standards for electronic health care transactions and addresses the security and privacy of health data. The initial deadline for standards compliance was October 2002, but has been extended to October 16, 2003.

This web site has a model compliance plan that can be completed and submitted to CMS on-line. There are instructions aplenty to help one complete the form.

There is also a smidge of explanation about HIPAA.



Concerns

Let us know what information you would like to see in the November issue of the Regulator. Write, phone, fax or e-mail your ideas.

Special points of interest:

? OSHA Directive



? Workforce Shortage



? New Surveyor



? Your Laboratory License

GA Point of Care Network Meeting

The Georgia Point of Care Network will present a seminar on Pulse Oximetry on September 20, 2002. The guest speaker will be Susan Blonshine, BS, RRT, RPFT, FAARC, AE-C. She is an author, educator, and consultant. Ms. Blon-

shine is also a member of the NCCLS Board of Directors.

The state lab folks will be there to go over the amended regulations and, of course, play stump the inspector.

This network group has

accomplished much since its' inception and the meetings are always well attended. The space is limited so the group urges you to RSVP early.

The meeting will be at the Children's Healthcare of Atlanta Office Park, 100 Tullie Circle (I-85 at N. Druid Hills Road). Please let them know by fax at 404-712-0819 or e-mail to karen_jenkins@emoryhealthcare.org. For more information call 404-686-1960. Carol, Diane, Karen, Becky, Regina and Jan, ya done good!

Osha restricts blood tube holder usage to a single event

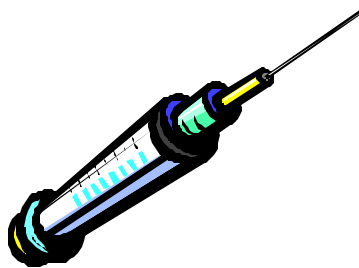
On November 27, 2001, OSHA issued a directive (CPL 2-2.26) that vacutainer holders must be discarded after a single use. The CDC published studies indicating that between 65 and 83 percent of the holders are contaminated after the first use.

OSHA has now taken the stance that twisting the needle so that it separates from the tube holder is an unacceptable practice.

The holders with needles must be used and immediately discarded, un-recapped, into accessible sharps

containers. The compliance directive is now being enforced.

You may find this information on the OSHA web site at: www.osha.gov. Go to the directives section or bloodborne pathogens and find CPL 2-2.6.



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Speaking of OSHA, the CDC has released draft guidelines for hand hygiene in hospitals and other healthcare settings. The guidelines call for the use of antiseptic gels rather than soap and water. BEWARE though, OSHA has not adopted this as a standard of practice yet. When compared to soap and water or even using antibacterial soap, the gel is more effective, stays on the skin longer, a sink isn't needed and takes less time!

Clinical laboratory workforce shortage.

Effective healthcare is always provided by a team of professionals. Lately, the news has been full of shortages in nursing, pharmacy and radiology. The laboratory shortage has gotten little publicity. However, did you know that clinical laboratory tests pro-

vide over 70 percent of the objective data used to make clinical decisions (ASCLS)?

Did you know that half of the accredited training programs in the U.S. were closed during the past 25 years? Most of the closures were due to the expense of train-

ing laboratory professionals, but lately, closures have been due to lack of students entering the field (BLS).

Data from the Bureau of Labor Statistics show that the lab workforce shortage is growing by 5,000 workers per year. This data was obtained from Dr. Lester Hardigree at Armstrong State, ASCLS national office and the Bureau of Labor Statistics.

There are 170,926 registered laboratories in the United States performing 7.25 billion laboratory tests a year.

Clia related news*****

You can go directly to CLIA's web site to find out the latest information on the CLIA program: <http://cms.hhs.gov/clia>. CLIA requires laboratories to notify the state agency (us) of changes in address, name or

director within 30 days of the change.

FDA has approved the Metrika A1c Now for professional use and the Metrika A1c Now for prescription home use as waived tests.

They also approved the Cholestec GDX A1C Test for prescription home use as a waived test. The Polymer Technology Systems Bioscanner 2000 PTS Panels Triglyceride Test Strips has been approved for OTC use.

Ten commandments for laboratory personnel

1. Thou shalt use only grounded outlets for analyzers, lest ye be elevated to a higher power.
2. Thou shalt not substitute the reference laboratory's proficiency testing results for thine own, lest thy license be revoked.
3. Thou shalt not use expired reagents, media or kits, lest ye bring down the wrath of the manufacturer and the inspectors.
4. Thou shalt take the sales hyperbole with a grain of salt and not as gospel; ye must research diligently.
5. Thou shalt document, document, document!!!
6. Thou shalt not commit erroneous testing without practicing remedial action.
7. Thou shalt have no untrained, unevaluated testing personnel.
8. Thou shalt have a quality assurance program that is perfect for thy facility.
9. Thou shalt follow manufacturer recommendations for testing unless the state or federal gods deem it unwise.
10. Thou shalt consider thy inspectors recommendations, that thy days may be long in the laboratory.

Little known and lightly regarded author: Anonymous B. Logan



Your laboratory license

A license can be issued to a laboratory **only** after all requirements for licensure are met.

The license must specify the name of the owner, director and the location of the laboratory.

A license is valid only for the laboratory at the stated location and

shall not be the subject of sale or transfer to any premises other than those for which it was issued.



If the lab changes location or ownership, a new application and another fee is required. All changes must be

in writing. A license must be publicly displayed at all times.

Laboratory licenses must always be current and up-to-date. Changes in categories/subcategories cannot be implemented without **prior** notification **and** approval by the Department.

Please note that specimen collection stations, even those under a parent lab, must be inspected prior to opening.

All fees are nonrefundable.

More interesting web sites

The FDA has a web site that provides information about safety issues involving medical products, including drugs and laboratory testing systems. You can also leave messages about problems that you have experienced or are having with test systems. Oh, Goody, a place to vent! The

web site is: www.fda.gov/medwatch/index.html.

Another good place to check out **and** use is www.quackwatch.com. This site was set up by a physician to expose medical scams. Some of the information here will tickle your funny bone and infuriate you at the same time. You may also submit your

concerns to this web site.

Some of the acceptable credentialing agencies now have web sites. Here are a few:

ASCP= www.ascp.org/bor

NCA= www.nca.info.org

AAB= www.aab.org

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We have a new surveyor by the name of Kay Shaw. She has been in Georgia for a number of years, but watch out, she is a Texas native. You know, everything is bigger and better.....

*Protecting Public Health and Safety Through
Regulatory Oversight*

BIOTERRORISM!

ARE YOU READY???????????

Don't forget to e-mail us your e-mail address. Send it to:
bjlogan@dhr.state.ga.us

Meet The DSU Lab staff

Bettie Council

Bettie is an honest-to-goodness Yankee, hailing from Cleveland, Ohio. All is not lost though. She has been south long enough to have learned how to drive and thus is not responsible for the constant traffic snarls.

Bettie has a major in Medical Technology and is a graduate of Fairview Hospital School of Medical Technology in Lakewood, Ohio.

Bettie has been a lab surveyor in Georgia since 1974. We think

she is the longest running surveyor in captivity.

She has a handsome furry sooner son named Mack. He is one very spoiled dog.

Bettie's hobbies include traveling, specifically the islands, her grandson, granddaughter and trying to keep pace with her mother.

Now, folks, Bettie does have one flaw that we have been able to find in all these years. She has a personality conflict with every



computer that has ever been within ten feet of her. She has been known to talk to them in a forceful manner. Last time I went past her cubicle, I could have sworn I heard her begging "Norman", her computer to work. Maybe there is hope for her yet in this new century!

